Complete Summary

GUIDELINE TITLE

Guidelines for outpatient prescription of oral opioids for injured workers with chronic, noncancer pain.

BIBLIOGRAPHIC SOURCE(S)

Washington State Department of Labor and Industries. Guidelines for outpatient prescription of oral opioids for injured workers with chronic, noncancer pain. Olympia (WA): Washington State Department of Labor and Industries; 2000 May 1. 17 p. [29 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic, noncancer pain

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Anesthesiology
Family Practice
Internal Medicine
Physical Medicine and Rehabilitation

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To supplement the 1998 Guidelines for Management of Pain issued by the Washington State Department of Health (DOH)
- To help doctors apply Department of Health guidelines to the care of injured workers with chronic, noncancer pain

TARGET POPULATION

Injured workers with chronic, noncancer pain who are taking opioids

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Baseline history and physical
2. Baseline pain and functional assessments
    - Function includes social, physical, psychological, daily and work activities
3. Baseline clinical or laboratory studies and/or urine drug screen

Treatment and Management

1. Office visits
2. Treatment agreements
3. Oral opioids
4. Participation in return-to-work programs
5. Consultations with employer, claim manager, vocational counselor, and others

MAJOR OUTCOMES CONSIDERED

- Pain relief and functional status
- Side effects
- Drug dependence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of the U.S. National Library of Medicine's Medline database to identify data related to the injured worker population.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Beginning in 1998 numerous meetings of the Treatment Guideline Subcommittee were devoted to discussion of medical, legal, adjudicative and other aspects of chronic pain management. The subcommittee carefully reviewed the medical literature on the topic of opioids and their use for chronic noncancer pain. The subcommittee refined a series of drafts, then used a consensus process to arrive at a draft for wider distribution and comment.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The subcommittee solicited and received comments from dozens of authorities from many parts of the United States. The authorities represented a spectrum of disciplines, specialties and perspectives, including non-physicians such as representatives of patient advocacy organizations.

After further discussion and incorporation of changes based on stakeholder input, the subcommittee presented a final draft to the Washington State Medical Association and recommended that the Washington State Medical Association approve the guidelines. The Washington State Medical Association approved the guidelines in April 1999. Additional comments were received, and the Washington State Medical Association approved a number of enhancements to the guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Summarized by the National Guideline Clearinghouse (NGC)

Section A: Assessment, Management and Documentation

1. Assessment of whether a formal trial of opioids for chronic pain is indicated

   The treating physician should address several questions to decide if a formal trial of opioids for chronic pain is indicated:

   - Are there reasonable alternatives other than opioids?
   - Is the patient likely to improve with opioids?
   - Is the patient likely to abuse opioids or have other adverse outcomes?

   See Table 1 below for guidance on the latter two questions.

   For guidance in the acute and subacute phases, refer to the "Guidelines for Outpatient Prescription of Controlled Substances for Workers on Time-Loss," developed in 1992 by the Washington State Department of Labor and Industries in collaboration with the Washington State Medical Association. These may be found in the Attending Doctor's Handbook, obtained by calling 1-800-848-0811.

   Beyond 2-4 months of acute/subacute opioid use, the following assessment is strongly recommended:

d. Perform a baseline history and physical, including pain history and the impact of pain on the patient, a complete exam, review of previous diagnostic and therapeutic results and an assessment of co-existing conditions.

e. Obtain relevant baseline clinical or laboratory studies and/or urine drug screen, as indicated.

f. Based on the results of the assessment, identify the pain diagnosis (See Table 1 below).

g. Baseline pain and functional assessments should be documented. It may be helpful to use a form like the Opioid Progress Report

Supplement found on page 16 of the original guideline document. Function includes social, physical, psychological, daily and work activities.

h. Assess the worker's ability to participate in a return-to-work program, for example, work-hardening and vocational services.
i. Assess likelihood the patient can be weaned from opioids in the event there is no improvement in pain and function.
j. The attending physician should determine whether he/she has the expertise to conduct a formal opioid trial for chronic pain. If not, the attending physician should make an appropriate referral.

Please note: In order for the Department of Labor & Industries or the self-insurer to pay for the opioid trial, the physician must submit a report no later than 30 days after beginning such treatment. [See Washington Administrative Code (WAC) 296-20-03020 for details on the requirements of this report.]

Table 1. How to Assess Whether an Opioid Trial is Indicated

Is the patient likely to improve?		Is the patient likely to abuse opioids or have other adverse outcomes?
MAY IMPROVE	PROBABLY WILL NOT IMPROVE	
11. Patient has taken opioids in the acute and subacute phases with some improvement in pain and function. 12. Other conservative measures have failed (nonsteroidal anti-inflammatory drugs [NSAIDs], etc.) and opioids have not been tried. 13. Pain diagnosis falls into one of the following three categories: • Nociceptive pain (e.g., ischemia, tissue destruction, arthritis, cancer, arachnoiditis). • Neuropathic pain (e.g., sciatica, carpal tunnel syndrome, trigeminal neuralgia, post-herpetic neuralgia,	14. Patient has taken opioids in the acute and subacute phases with NO improvement in pain and function (assuming appropriate dosing, etc.). 15. The pain diagnosis falls into the category of somatoform disorder. A consultation should be considered to address the underlying problem. In particular, conversion disorder, somatization disorder, or pain disorder associated with psychological factors [Diagnostic and Statistical	The risk of abuse or adverse outcome is high if any of the following are present: 16. History of alcohol or other substance abuse, or a history of chronic, high dose benzodiazepine use. 17. Active alcohol or other substance abuse. 18. Borderline personality disorders. 19. Mood disorders (e.g., depression) or psychotic disorders. 20. Other disorders that are primarily

phantom limb pain). • Mixed nociceptive and neuropathic pain.	Manual of Mental Disorders, Fourth Edition (DSM-IV) 307.80] is associated with poor response to opioids.	depressive in nature. 21. Off work for more than 6 months. 22. Poor response to opioids in the past. Note: When special circumstances seem to warrant the use of these drugs in the types of patients noted above, referral for review is indicated.

2. Management of a formal trial of opioids for chronic pain
The following general parameters should guide the attending physician's plan of care:

. Second opinion: Consider a second opinion before planning the trial of opioids to assess whether a trial is indicated, and if so, how it should be conducted.

a. Documentation: Use the one-page Opioid Progress Report Supplement, found on page 16 of the original guideline document. This will help with compliance for all documentation requirements of the Department of Labor and Industries. [See Washington Administrative Code (WAC) 296-20-03021 and 296-20-03022.] Using the one-page Opioid Progress Report Supplement will also serve as a step-by-step guide to remind the physician and the patient to address a number of key issues, such as the treatment agreement, screening for addiction, return-to-work efforts, assessment of functional progress, consultations, medication history, treatment plan, etc.

b. Contingency plan: Plan ahead of time for both of these possibilities:
   - The patient needs to be weaned from opioids because there has been no improvement in pain and function.
   - Continuation of opioids beyond maximum medical improvement is indicated, and other forms of payment for the medications will be needed.

c. Treatment agreement: The physician and the patient should together sign a treatment agreement that outlines: the risks and benefits of opioid use, the conditions under which opioids will be prescribed, the physician's need to document overall improvement in function, and worker responsibilities (See Appendix 3 of the original guideline document, pages 14-15, â œSample Opioid Treatment Agreementâ).

Safety risks: Patients should especially be warned about potential side effects of opioids such as increased reaction time, clouded judgment, drowsiness and tolerance. Also, they should be warned

about the possible danger associated with the use of opioids while operating heavy equipment or driving.

d. Helping the patient return to work: The physician should participate in a team conference with the patient, the employer (or potential new employers), the claim manager, the vocational counselor and others (preferably face-to-face) to explore return-to-work options. Which parties need to be involved will vary with each situation. Phone conferences often work well. For more information on available resources, see pages 9 – 14 of the Attending Doctor's Handbook (available at 1-800-848-0811).

e. Principles for prescription of opioids: The physician should follow these general principles:
   - Single prescribing physician: There should be a single prescribing physician for all controlled substances.
   - Single pharmacy: Use a single pharmacy for prescription filling (whenever possible).
   - Lowest possible dose: The lowest possible effective dose should be used to initiate therapy, and should be titrated, as needed to minimize both pain and medication side effects and maximize pain management and increased functioning.
   - Appearance of misuse of medications: Be sure to watch out for and document any appearance of misuse of medications. Acquisition of drugs from other physicians, uncontrolled dose escalation or other aberrant behaviors must be carefully assessed. In all such patients, opioid use should be reconsidered and additional, more rigid guidelines applied if opioids continue. In some cases, tapering and discontinuation of opioid therapy will be necessary.

f. Visit frequency: Visits initially at least every 2 weeks for the first 2-4 months of the trial, then at least once every 6-8 weeks while receiving opioids.

g. Consultations: Request a consultation if:
   - A dose in excess of 100-150 mg of oral morphine daily or its equivalent (for example, 45 mg of MS Contin every 8 hours) is being used;
   - Pain and functional status have not substantially improved after 3 months of opioid treatment;
   - A patient has a history of chemical dependency; or
   - A patient appears to have significant problems with depression, anxiety or irritability (a psychologic consultation may be indicated in these cases).

h. Laboratory studies and drug screens: Remember to order relevant ongoing clinical or laboratory studies (especially liver or kidney function screens), including drug screens, as indicated.

i. Discontinuation vs. continuation of opioids: After 6 months of a well-designed opioid trial, a physician should determine whether opioid therapy is appropriate for the patient, in accordance with the following:
   - If there has not been an overall improvement in function, opioids should usually be discontinued. (If there are extenuating circumstances that justify further use of opioids

after 6 months of an opioid trial, these should be described in detail.)

- If the patient has returned to work or has demonstrated substantial improvement both in function and reported pain level during a 6-month opioid trial, reasonable doses of opioids could continue. However, the physician and patient should understand that state law forbids the Department of Labor and Industries (L&I) from paying for opioids once the patient reaches maximum medical improvement. Please refer to the Department of Labor and Industries' Medical Aid Rules Washington Administrative Code (WAC) 296-20-03019 through 296-20-03024 for further details. The physician should speak with the patient about other sources of payment for opioids when the Department of Labor and Industries (L&I) can no longer pay. With this in mind, the physician should re-evaluate the need for opioids every two months, using techniques such as weaning and/or substitution of alternative treatments.
- Weaning time: Weaning can be done safely by way of a slow taper. Patients who undergo intensive treatment programs in a pain center or a drug rehabilitation center can be tapered off opioids in 1-2 weeks. Patients being treated in an office-based practice should be tapered more slowly, but the taper should never take more than 3 months.

Section B: Long-term Issues

1. What should the physician do with a patient who has already been on opioids for 6 months or more and is not back at work (or for a new patient like this)?

   If a patient has already received opioids for six months or more, the physician should do the following:

   a. Re-assess: Perform a thorough re-assessment of the patient to see if anything has been missed.
      - Is the original diagnosis still present? Are there additional diagnoses that may contribute to the pain?
      - Has the patient been given other medications for management of pain? If so, how effective were they, what side effects were experienced and how severe were the side effects?
      - Has the patient tried other treatment methods or consulted with other specialists? If so, what alternative methods have been tried, length of alternative treatments, effectiveness, and/or specialist recommendations and effectiveness of those recommendations?
      - Has there been functional improvement since opioids were started? Try to quantify the improvement.
      - Would a psychological or psychiatric evaluation, completed by a psychiatrist or psychologist experienced in evaluating chronic pain patients, be helpful or necessary to determine effective pain management for this patient? Or has the patient completed a similar evaluation within the last 3-6 months?

Psychosocial issues include motivation, attitude about pain/work, return-to-work options, home life, etc.
- Has screening for elements of addiction been completed? Special caution should be exercised in patients with a history of substance abuse that cannot be attributed to a past mistaken diagnosis of addiction because this patient previously used opiates for pain management. Has there been a review of prior medical records, including the Department of Labor and Industries' (L&I) medical records and drug summaries? A drug summary may be obtained from the claim manager.
- Review Sections A2, C1 and C2 for guidance on re-assessment and documentation. The essential material in these sections, particularly the treatment plan and its relationship to recovery, should be covered in the summary.

b. Summarize: The insurer and others involved in the patient's care should be provided with a written summary of the case. Special attention should be given to the history of opioid use (how long, in what doses, etc.). A clear statement of the rationale should be given if the treating physician thinks opioid treatment should continue.

c. Help the patient return to work: The physician should participate in a team conference with the patient, the employer (or potential new employers), the claim manager, the vocational counselor and others (preferably face-to-face) to explore return-to-work options. Which parties need to be involved will vary with each situation. Phone conferences sometimes work well.

   For more information on available resources and how to bill for these services, see pages 9 – 14 of the Attending Doctor's Handbook (available at 1-800-848-0811).

d. Triage: If the patient has been treated with opioids for 6 months or more, the physician should automatically review the case as described in a) through d) above. At that point the physician should choose one of three pathways:
   - Modify the treatment plan to achieve optimum opioid benefit. Many patients like this will be taking combinations of medications that don't offer optimal pain control.
   - Discontinue opioid therapy.
   - Continue in opioid therapy.

   In the third pathway, plans could be made to eventually move from the long-term opioid pathway up to one of the other pathways.

Section C: Precautions in Prescribing

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1. What precautions should be taken when prescribing opioids?
   a. DO NOT USE:
      Opioids in combination with sedative-hypnotics (such as benzodiazepines or barbiturates) for chronic, noncancer pain. (There may be specific indications for such combinations, such as the co-

existence of spasticity. In such cases, a consultation is strongly recommended.)

b. Use of these medications is NOT RECOMMENDED:
    - Meperidine, which should not be prescribed for chronic pain.
    - Tramadol (Ultram) in combination with other opioids.
    - Carisoprodol (Soma).
    - Combination agonists and mixed agonists/antagonists. Mixed agonists/antagonists include such drugs as butorphanol (Stadol), dezocine (Dalgan), nalbuphine (Nubain) and pentazocine (Talwin).
    - Barbiturates (except if used to treat a seizure disorder).
    - Outpatient prescriptions of parenteral dosage forms of any drug.

c. Use caution when prescribing:
    - Acetaminophen in doses greater than 4 grams (including, for example, combinations of drugs that include both an opioid and acetaminophen).
    - Cyclobenzaprine (Flexeril) in combination with tricyclic antidepressants (both share the same toxic potential).
    - Nonopioid drugs concomitantly with combination opioids (e.g., Tylenol given with Percocet).
    - Tramadol (Ultram) to patients at risk for seizures and/or who are also taking drugs that can precipitate seizures (e.g., SSRI antidepressants, tricyclic antidepressants).
    - Opioids, including tramadol, to patients with a prior or active history of chemical dependency.

d. Other recommendations include:
    - Drug therapy should be individualized to the patient's specific pain condition and chosen on the basis of each drug's pharmacologic activity.
    - Maintain patients on as few medications as possible. Drug interactions and adverse events increase as the number of medications in a regimen increases.
    - Use adjuvant medications that are specific for a given pain condition.
    - If possible, titrate only one drug at a time, while observing the patient for additive effects. Inappropriate medications should be tapered while initiating an appropriate pharmacologic regimen.

2. What signs may be seen in a person with a prescription opioid problem?

   The following guidelines were developed in a pain clinic setting. These guidelines may be a useful monitoring tool in managing chronic pain patients in the office setting. A patient may qualify as a prescription opiate abuser by meeting three or more of the criteria listed below. Physicians are encouraged to seek consultations (addictionologist, pain clinic, etc.) if 3 or more of these criteria are met. The patient:

   a. Displays an overwhelming focus on opioid issues. For example, discussion of opioids occupies a significant portion of the visit and

impedes progress with other issues regarding the patient's pain. This behavior persists beyond the third clinic session.

b. Has a pattern of early refills (3 or more) or escalating drug use in the absence of physician direction to do so.
c. Generates multiple telephone calls or visits to the office to request more opioids, early refills, or problems associated with the opioid prescription. A patient may qualify with fewer visits if he or she creates a disturbance with the office staff.
d. Demonstrates pattern of prescription problems for a variety of reasons that may include lost medications, spilled medications or stolen medications.
e. Has supplemental sources of opioids obtained from multiple providers, emergency rooms or illegal sources.
f. Has illicit drugs on urine screen.

CLINICAL ALGORITHM(S)

The guideline contains a flowchart summarizing opioid guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

With appropriate patient selection and careful monitoring, opioid treatments can be effectively provided to injured workers with chronic, noncancer pain. Careful, regularly documented compliance with this guideline is necessary for the safety of injured workers, and to further the goal to return injured workers to health and to work.

Subgroups Most Likely to Benefit:

- Patients who have taken opioids in the acute and subacute phases with some improvement in pain and function.
- Patients in whom other conservative measures have failed (Nonsteroidal anti-inflammatory drugs, etc) and opioids have not been tried.
- Patients whose pain diagnosis falls into one of the following three categories:
    - Nociceptive pain (for example, ischemia, tissue destruction, arthritis, cancer, arachnoiditis).
    - Neuropathic pain (for example, sciatica, carpal tunnel syndrome, trigeminal neuralgia, post-herpetic neuralgia, phantom limb pain).
    - Mixed nociceptive and neuropathic pain.

POTENTIAL HARMS

Opioid Therapy:

- Side effects of opioids include increased reaction time, clouded judgment, drowsiness and tolerance.
- Operating heavy machinery, driving motor vehicles and other work activities may be dangerous to the patient and to his/her co-workers if controlled substances are used. A patient's livelihood may be affected for this reason.
- There is a risk of abuse of opioids, especially after long-time use.

Subgroups Most Likely to be Harmed:

The risk of abuse or adverse outcome is high if any of the following are present:

- History of alcohol or other substance abuse, or a history of chronic, high dose benzodiazepine use
- Active alcohol or other substance abuse
- Borderline personality disorders
- Mood disorders (e.g., depression) or psychotic disorders
- Other disorders that are primarily depressive in nature
- Off work for more than 6 months
- Poor response to opioids in the past

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The medical care a patient receives is a matter of choice for the patient to make in consultation with a treating physician. This principle is the same in cases with and without workers' compensation issues. Payment for medical care involves issues that may be distinct from treatment decisions. The Department of Labor and Industries pays for only that medical care that meets the requirements of the Washington Administrative Code and cannot pay for opioids once the patient reaches maximum medical improvement.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The guidelines became effective January 20, 2000 (along with the payment rules). The payment rules were mailed to all effected providers in PB 00-01, in January 2000. The guidelines were mailed to the same providers, together with the payment rules, in PB 00-04, in May 2000. To encourage providers to be familiar with the new guidelines, the department offered a self-assessment test and free Continuing Medical Education (CME). This self-assessment test was included in PB 00-04. Continuing Medical Education is available for tests received on or before 3/1/03.

The guideline developer's claim adjudicators had to attend a 4 hour mandatory training on the guidelines and their use in authorizing treatment for injured

workers. The training included a specific, written process for the adjudicators to follow.

In addition, one of the guideline developer's associate medical directors, Dr. Hal Stockbridge, provided training to health care providers, self-insurers and other groups and individuals in a variety of settings since the guidelines and rules took effect.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Washington State Department of Labor and Industries. Guidelines for outpatient prescription of oral opioids for injured workers with chronic, noncancer pain. Olympia (WA): Washington State Department of Labor and Industries; 2000 May 1. 17 p. [29 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 May 1

GUIDELINE DEVELOPER(S)

Washington State Department of Labor and Industries - State/Local Government Agency [U.S.]
Washington State Medical Association - Medical Specialty Society

SOURCE(S) OF FUNDING

- Washington State Department of Labor and Industries
- Washington State Medical Association

GUIDELINE COMMITTEE

Washington State Medical Association (WSMA) Industrial Insurance Advisory Committee, Washington State Department of Labor and Industries (L&I)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The individual names of the Washington State Medical Association (WSMA) Industrial Insurance Advisory Committee are not provided in the original guideline document.

Name of the Medical Director, Washington State Department of Labor and Industries (L&I): Gary Franklin, M.D.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Please note: This guideline has been updated. The National Guideline Clearinghouse is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available as an appendix to the guideline:

- Washington State Department of Health (DOH). Medical Quality Assurance Commission. 1998 Guidelines for management of pain. Olympia (WA): Washington State Department of Health (DOH), 1998. 3 p.

Print copies: L&I Warehouse, Department of Labor and Industries, P.O. Box 44843, Olympia, Washington 98504-4843.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 28, 2001. The information was verified by the guideline developer as of May 4, 2001.

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